Puget Sound Blood Center
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December 9, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: **Docket 98N-0607**
General Requirements for Blood, Blood Components, and Blood Derivatives; Notification of Deferred Donors

To Whom It May Concern:

The Proposed Rule, "General Requirements for Blood, Blood Components, and Blood Derivatives: Notification of Deferred Donors," seeks to codify what the FDA generally sees to be current industry practice. Much of this current practice, however, such as additional testing, donor notification, and donor education, is outside the authority of the FDA. These activities do not materially affect the safety, potency, or purity of blood components.

The tests to be performed, behaviors to be rejected, and communicable disease risks to be eliminated are already regulated, and the donor is deferred accordingly. The auxiliary activities described in the Proposed Rule involve interactions between blood establishments and their donors relating to the practice of medicine and other ethical ideals, not product safety, purity, or potency. As such they vary from one establishment to another, one State to the next, and require flexibility to the approach, not needless rulemaking and federal red tape.

It is unnecessarily burdensome and overly taxing to mandate not only general principles of donor notification but the minutia detailed in the Proposed Rule and the preamble. The proposed rule imposes upon blood establishments a public health function. This exceeds the statutory authority of the FDA.

The following specific comments also apply:

1. The requirement for proof of a permanent address:

   Although it is not unreasonable that the blood establishment obtain the donor's "permanent" address, it must be recognized that "permanent" addresses change and that "permanent" could be variously defined. The proposed Section 606.100(b)(1)(x) states that the donor's permanent address be on record. The difficulty comes in the preamble which states that "proof" of permanent address be required before a donor can donate. First, this requirement is unnecessary. There is no incentive for a voluntary blood donor to provide a falsified or inadequate address. It makes no sense to believe a donor's responses to high risk behavior questions yet refuse to believe that he is giving a correct address. Second, the requirement is excessively burdensome to both the volunteer donor and to the blood establishment. There is no reason to mandate the acquisition of information already obtained nor to define the degrees of proof required to fulfill the request. Finally, this requirement is impossible. There is no way that a donor can "prove" what his address is or

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that he intends to remain there indefinitely, nor, if he submits "proof", that the blood establishment can independently verify it.

2. Donor notification based on test results:

   Blood establishments already notify donors who test positive for infectious disease markers. They do this because they feel they have an obligation to their donors to inform them of results that may have personal or public health implications. This practice has nothing to do with the safety of the blood supply, since the donors are on the deferral registry with or without notification. It is unnecessary and overly burdensome for the FDA to attempt to micromanage these notification processes.

   Although primarily dealt with in a different rule, mention is made in this proposed rule that, if available, supplemental testing be done for all positive viral markers. This is not a reasonable requirement. From the point of view of the FDA and the safety of the blood supply, the value of supplemental testing is only to determine which donors can be safely reentered. Appropriate medical follow-up of donors who test positive is primarily the job of the donor's health care provider, not the blood establishment. Although many blood establishments do perform supplemental testing as a service to their donors, it should be of no concern to the FDA whether supplemental testing is performed or, if it is performed, whether it is performed by the blood establishment or the donor's physician. It is an attempt to regulate the practice of medicine and should be eliminated.

3. Donor notification based on donor suitability:

   Donors deferred for suitability criteria are already informed at the time of attempted donation of the reason for deferral and its duration. There is no need to further regulate this process. Additional regulations regarding the details of this process will only complicate matters, introduce further opportunities for error, and increase the cost. There will be no effect on the safety of the blood supply; thus these activities are not really appropriate for FDA regulation.

   Notification of donors with positive tests and notification of donor who fail suitability requirements are very different matters. In the former, it is known that the donor has a problem. In the latter, it is very unlikely that the donor has a problem. This is because, appropriately, the threshold for failure of a suitability criteria is set very conservatively, to exclude donors who have only a remote chance of transmitting any infection. To suggest the same notification procedure for the two circumstances is unreasonable.

   For the vast majority of such donors, it is not appropriate that they be referred for treatment or further medical counseling and to require so would be excessive. In the case of previous transplantation, blood transfusion, or human pituitary-derived growth hormone, it was a physician who prescribed the disqualifying event. For a donor who had resided in the United Kingdom, a recommendation that she see her family physician would be ridiculous. In fact, from the point of view of the donor's health, it is much more important to refer for medical follow-up a donor with extreme hypertension, or even a low hemoglobin,

than a donor who has failed a communicable disease suitability criterion. These decisions are best left in the hands of the medical expertise at the blood establishment and not codified by regulation. Furthermore, these regulations might create a physician-patient relationship between the donor and the blood establishment. To require a procedure that would create such a relationship would both exceed FDA authority and conflict with statutes prohibiting the corporate practice of medicine.

It is also not necessary to require that these donors be counseled about the risk of transmitting communicable disease. To do so would require blood establishments to play by rules much more stringent than practiced by the medical community or by public health entities. None of these entities would spend any effort running down individuals who had stuck themselves with a needle or traveled to Mexico or had a tattoo for the purpose of counseling.

4. Do autologous donors need to be notified of abnormal test results?

   Although most blood establishments perform some sort of notification if abnormal results are obtained for autologous donors, such notification has no effect on the safety of the blood supply and should not be a concern of the FDA. In the case of an autologous donation, the patient is under the care of a physician and the blood draw is a procedure that is prescribed by the patient's physician. As such it is perfectly reasonable that reports of abnormal results be addressed to the patient's physician rather than to the patient directly. In virtually all other medical settings, reports of laboratory tests or procedures that are ordered by the physician go to the physician, not the patient. One could reasonably argue that direct notification of the patient would be interfering with the role of the patient's physician. It should thus be at least equally acceptable, if not preferable, for notification to be given to the patient's physician.

5. Should donors with one-time positive a-HBc or a-HTLV I/II be notified?

   The reliability of these tests is low enough that a one-time positive is not grounds for deferral. For the same reason, notification should not be required. It would be difficult to construct a useful message for such a donor, and notification would serve little purpose other than to alarm the donor and possibly drive him away from future donation.

6. It is stated in the preamble that donors with one repeat reactive HTLV I/II would be deferred if a supplemental test were performed. This statement should be clarified to apply only if the supplemental test was positive (or, at least, not negative).

Sincerely,

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Medical Director

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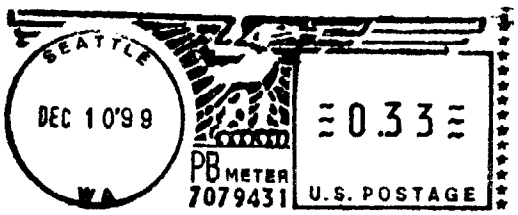

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